

REMARKS

Claims 1-14 were pending. The Examiner withdrew claims 3 and 5-9 from consideration as being drawn to a nonelected invention. Claims 1, 2, 4, and 10-14 are pending and under examination.

I. Rejection of Claims 1-2, 4, and 10-14 under 35 U.S.C. § 112, first paragraph

The Office rejected claims 1, 2, 4, and 10-14 under 35 U.S.C. § 112, first paragraph, as allegedly failing to comply with the written description requirement. Office Action at page 3, item no. 6. The Office alleges that “[t]he claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.” *Id.* Applicants respectfully traverse the rejection.

The Office acknowledged that “[t]he specification as filed provides sufficient description for the skilled artisan to predict the structures of antisense constructs that produce an antisense RNA have a sequence that is fully complementary to SEQ ID NO: 7, 9, or 11, wherein the antisense RNA is effective for suppressing the enzyme activity of cellobiohydrolase 1 gene, having a sequence according to SEQ ID NO: 7, 9 or 11.” Office Action at page 4. However, the Office alleges that “Applicants have not described the structures of the full scope of cellobiohydrolase 1 genes encompassed by the instant claims, such that the skilled artisan would be able to predict the structures of the full scope of antisense constructs encompassed by the instant claims.” *Id.* at pages 4-5. The Office further alleges that “other than the full-length sequences of SEQ ID NO: 7, 9, or 11, wherein said sequences have cellobiohydrolase 1 activity, the specification as filed does not provide a clear correlation between modified, mutated, polymorphic, or allelic variant forms of these sequences, wherein said sequences comprises

deletions, substitutions or additions, and maintains cellobiohydrolase 1 activity.” *Id.* at page 5. The Office also alleges that “to the extent that Applicants are not in possession of the full scope of nucleic acid sequences . . . encompassed by the instant claims, Applicants are not in possession of the full scope of antisense constructs encompassed by the instant claims. . . .” *Id.* Applicants traverse the rejection and assert that the specification describes the full scope of “DNA encoding an antisense RNA substantially complementary to the whole or a part of a transcription product of a cellulolytic enzyme gene [e.g., cellobiohydrolase I] derived from Basidiomycete” according to the claims, in sufficient detail that one skilled in the art would reasonably conclude that the Applicants had possession of the claimed invention at the time the application was filed.

First, Applicants respectfully remind the Office that “[t]here is a strong presumption that an adequate written description of the claimed invention is present in the specification as filed [and c]onsequently, rejection of an original claim for lack of written description should be rare.” M.P.E.P. § 2163 at 2100-169 (Rev. 5, Aug. 20006). Applicants also respectfully remind the Office that claims 1, 2, 4, 13 and 14 are original claims, and claims 10-12 were amended merely to remove multiple claim dependencies.

Next, the Office noted that the M.P.E.P. states “[a] biomolecule sequence described only by a functional characteristic, without any known or disclosed correlation between that function and the structure of the sequence, normally is not a sufficient identifying characteristic for written description purposes. . . .” Office Action at page 6. Applicants respectfully point out, however, that “there is no per se rule that an adequate written description of an invention that involves a biological macromolecule must contain a recitation of known structure.” M.P.E.P.

§ 2163 at 2100-172. In any event, the claims do, in fact, recite a structure, a nucleotide sequence, which is correlated to a function of suppressing cellobiohydrolase I activity.

In addition, “a claim which encompasses two or more embodiments or species within the scope of the claim is analyzed as a claim drawn to a genus.” *Id.* at 2100-173 to 2100-174. The Office has implicitly recognized that the claims encompass a genus by acknowledging that certain embodiments are adequately described, while alleging that others are not. *See* Office Action at pages 4-5. Accordingly, it is clear that the Office has determined that the claims encompass two or more embodiments, and, as provided by the M.P.E.P., the claims must be analyzed as being drawn to a genus.

The M.P.E.P. provides guidance for analyzing claims drawn to a genus for satisfaction of the written description requirement as follows:

[t]he written description requirement for a claimed genus may be satisfied through sufficient description of a representative number of species by actual reduction to practice . . . , or by disclosure of relevant, identifying characteristics, i.e., structure or other physical and/or chemical properties, by functional characteristics coupled with a known or disclosed correlation between function and structure, or by a combination of such identifying characteristics, sufficient to show the applicant was in possession of the claimed genus.

Id. 2100-175. In addition, the M.P.E.P. explains that

[w]hat constitutes a “representative number” is an inverse function of the skill and knowledge in the art [and] depends on whether one of skill in the art would recognize that the applicant was in possession of the necessary common attributes or features of the elements possessed by the members of the genus in view of the species disclosed. . . . Description of a representative number of species does not require the description to be of such specificity that it would provide individual support for each species that the genus embraces.

Id. at 2100-176.

Applicants assert that the specification discloses the actual reduction to practice of at least a representative number of species, and in addition, provides disclosure of relevant,

identifying characteristics, “sufficient to show the applicant was in possession of the claimed genus” at the time the application was filed.

First, certain exemplary cellulolytic enzyme genes, including cellobiohydrolase I genes, are described in the specification as follows. The nucleotide sequence of cellobiohydrolase I-1 gene from *Coriolus hirsutus* is provided as SEQ ID NO: 7, a 1496-bp nucleotide sequence. *See, e.g.*, Specification at page 37, SEQ ID NO: 7. The nucleotide sequence of cellobiohydrolase I-2 gene from *Coriolus hirsutus* is provided as SEQ ID NO: 9, a 1488-bp nucleotide sequence. *See, e.g.*, Specification at page 38, SEQ ID NO: 9. The nucleotide sequence of cellobiohydrolase I-3 gene from *Coriolus hirsutus* is provided as SEQ ID NO: 11, a 1485-bp nucleotide sequence. *See, e.g.*, Specification at page 39, SEQ ID NO: 11. Applicants note that each of these genes contains a different sequence and is of a different length from the others, thus providing express support for “modified, mutated, polymorphic, or allelic variant forms of these sequences, wherein said sequences comprises deletions, substitutions, or additions, and maintains cellobiohydrolase 1 activity.” *See* Office Action at page 5.

In addition, the specification provides a detailed description of certain physicochemical properties of cellobiose dehydrogenase protein encoded by a cellobiose dehydrogenase gene (e.g., cellobiohydrolase I) used in the methods of the claims. Specification at pages 29-31. For example, the specification describes how to measure cellobiose dehydrogenase enzyme activity, and provides substrate specificity, optimal pH and stable pH range, range of temperatures for measuring enzyme activity, isoelectric point, molecular weight, and influence of certain inhibitors, e.g., metal ions, on enzyme activity. *Id.*, and Figures 1-5. The specification also refers to several publications concerning cellobiose dehydrogenase from other species and identifies certain differences in the properties of those enzymes. Specification at pages 32-34.

Accordingly, the specification provides an ample description of how to measure and assess the enzyme activity of various cellobiose dehydrogenase (e.g., cellobiohydrolase I) proteins from *Coriolus hirsutus* as well as from other species. Therefore, the specification clearly discloses at least a representative number of “modified, mutated, polymorphic, or allelic variant forms of these sequences, wherein said sequences comprises deletions, substitutions, or additions, and maintains cellobiohydrolase I activity.” See Office Action at page 5.

Moreover, the specification describes at least a representative number of DNA encoding an antisense RNA substantially complementary to the whole or a part of a transcription product of a cellulolytic enzyme gene, e.g., cellobiohydrolase I. For example, Examples 14-16 at pages 45-46 of the Specification describe the construction of three different plasmids, each having a different antisense sequence of cellobiohydrolase I gene from *Coriolus hirsutus*. The antisense sequence in each of the examples was approximately 750-bp, *id.*, clearly indicating that the inventors had reduced to practice at least a representative number of antisense sequences substantially complementary to a part of a transcription product of cellobiohydrolase I.

In addition, the level of skill and knowledge in the art of antisense RNA was high at the time the application was filed. For example, the specification teaches that “[p]reparation of antisense RNA and use of the sequence are carried out by conventional methods known to a person skilled in the art.” Specification at page 24. Because that statement refers to “conventional methods” used to prepare antisense RNA, it strongly suggests that the field was well-developed and mature at the time the application was filed. The specification further teaches several exemplary ways to obtain an antisense RNA of a cellulolytic enzyme gene, which includes performing PCR on a cellulolytic enzyme gene, digesting a cellulolytic enzyme gene with appropriate restriction enzymes, or synthesizing RNA on the basis of the information

on the nucleotide sequence of a cellulolytic enzyme gene. Specification at pages 24-25. All of those are conventional methods known to one skilled in the art at the time the application was filed. Accordingly, based on the description in the specification coupled with the high level of skill and knowledge in the art of antisense RNA, one skilled in the art would reasonably conclude that, at the time the application was filed, the inventors had reduced to practice at least a representative number of DNA encoding an antisense RNA substantially complementary to the whole or a part of a transcription product of a cellulolytic enzyme gene derived from Basidiomycete, e.g., cellobiohydrolase I, and therefore, were in possession of the claimed genus.

Furthermore, in addition to describing at least a representative number of DNA encoding an antisense RNA substantially complementary to the whole or a part of a transcription product of a cellulolytic enzyme gene, e.g., cellobiohydrolase I, the specification also describes preparing at least a representative number of vectors comprising DNA, transforming host cells with vectors, and host cells having suppressed cellulolytic enzyme activity, e.g., cellobiohydrolase I enzyme activity, according to the claimed methods. The Specification teaches vectors and the preparation of vectors comprising DNA encoding an antisense RNA, for example, at page 26 and Examples 14-16. The Specification teaches host cells and transforming host cells with vectors, for example, at pages 26-27 and Examples 29, 34, and 39. The Specification teaches host cells having suppressed cellobiohydrolase I enzyme activity, for example, at pages 26-27 and Examples 29, 34, and 39. Accordingly, the Specification provides an ample description of at least a representative number of species and, therefore, one skilled in the art would reasonably conclude that the inventors were in possession of the claimed genus at the time the application was filed. Accordingly, the specification supports the full scope of claims 1, 2, 4, and 10-14. Thus, Applicants respectfully request reconsideration and withdrawal of the rejection of claims

1, 2, 4, and 10-14 under 35 U.S.C. § 112, first paragraph, as allegedly failing to comply with the written description requirement.

II. Rejection of Claims 12-14 under 35 U.S.C. § 102(b).

The Office rejected claims 12-14 under 35 U.S.C. § 102(b) as allegedly being anticipated by Chen et al. (Chen, *Wood and Fiber Science*, 27(2):198-204, 1995; “Chen”). Office Action at page 6, item no. 9. Applicants respectfully traverse that rejection.

First, Applicants respectfully point out that the Office did not provide fully and clearly stated grounds for the rejection. See M.P.E.P. § 707.07(d) at 700-125 (Rev. 5, Aug. 2006). The Office merely stated that “Chen et al. discloses a method for pulping comprising treating wood chips with ‘white rot.’ See Results and Discussion section on page 200 of this reference.” Office Action at page 6. The Office never indicated which aspect of the “Results and Discussion section on page 200” is relevant to the rejection, nor did the Office explain how any purported disclosure in Chen allegedly anticipates claims 12-14. Accordingly, the Office has provided an insufficient basis for the rejection of claims 12-14 under § 102(b) in view of Chen. Applicants respectfully request reconsideration of the rejection, particularly in view of the following arguments.

As set forth in the M.P.E.P., “[a] claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference.” M.P.E.P. § 2131 at 2100-67 (Rev. 5, Aug. 2006) (citing *Verdegaal Bros. v. Union Oil Co. of California*, 2 USPQ2d 1051, 1053 (Fed. Cir. 1987)). Notwithstanding the Office’s failure to provide a sufficient basis for the rejection, Applicants assert that, in any event, Chen does not anticipate any of claims 12-14 for at least the following reasons. Claim 12 recites “[a] woodchip obtained by the method according to claim 1.” Therefore, claim 12 depends from

claim 1 and thus, necessarily includes all of the language of claim 1. As provided by statute, “a claim in dependent form shall contain a reference to a claim previously set forth and then specify a further limitation of the subject matter claimed. A claim in dependent form shall be construed to incorporate by reference all the limitations of the claim to which it refers.” 35 U.S.C. § 112, fourth paragraph.

Since the Office did not include claim 1 with the rejection of claims 12-14 under § 102(b) in view of Chen, it is clear that the Office determined that Chen does not anticipate claim 1. Because Chen does not anticipate claim 1, and claim 12 includes all of the language of claim 1, Chen likewise does not anticipate claim 12. In addition, for at least that reason, Chen also does not anticipate either of claims 13 or 14, which ultimately depend from claim 12, and therefore also include all of the language of claim 1. Accordingly, Applicants respectfully request reconsideration and withdrawal of the rejection of claims 12-14 under 35 U.S.C. § 102(b) as allegedly being anticipated by Chen.

CONCLUSION


In view of the foregoing amendments and remarks, Applicants respectfully request reconsideration and reexamination of the application and the timely issuance of a Notice of Allowance. If the Examiner does not consider the claims allowable, the undersigned requests that, prior to taking action, the Examiner call her at (650) 849-6749 to set up an interview.

Please grant any extensions of time required to enter this response and charge any additional required fees to Deposit Account No. 06-0916.

Respectfully submitted,

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